

Attorney Docket No: 38-15(52826)B

Remarks begin on page 7 of this paper.

Applicants submit this amendment in response to the Examiner's suggestions. The proposed amendments do not add new claims, do not raise the issue of new matter, and do not present new issues requiring further consideration or search. The proposed amendments simplify the issues under consideration. Applicants therefore respectfully request consideration and entry of the proposed amendments.

This response is being timely filed within three (3) months of that date and thus no extension of time is believed necessary. In the event that this paper is deemed not timely filed, Applicants hereby petition for an appropriate extension of time. The fee for this extension may be charged to Deposit Account No. 134,125 along with any other additional fees which may be required with respect to this paper; any overpayment should be credited to the account.

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**REMARKS****REASONS FOR AMENDMENTS****PRIORITY CLAIM**

Applicants request that amendment of page 1, first paragraph, be made to correct the specification in order to comply with the 35 USC §119 requirements for receiving benefit of the earlier filing date of provisional application 60/434,242 filed on 18 December 2002, priority to which was claimed in Applicants' declaration for the present application.

This amendment does not add new material to the application.

Applicants acknowledge the Examiner's withdrawal of all other objections to the specification.

**CLAIMS**

Applicants request that amendment of claims 1, 3, 5, 14, 16, and 18 be made. As more specifically discussed below, Applicants believe these amendments place the claims in condition for allowance as well as present the claims in better form for consideration on appeal and reduce issues of patentability under §112 relating to indefiniteness, written description, and enablement. None of these amendments add new material to the application.

**REJECTIONS****CLAIMS ARE DEFINITE UNDER 35 USC §112, SECOND PARAGRAPH**

The Examiner has rejected claims 1 – 17 as being indefinite for failing to particularly point out and distinctly claim the subject matter which applicants regard as the invention. Applicants believe that the claims as originally filed, and as previously amended, are definite under 35 USC §112, second paragraph. Nonetheless, to expedite allowance of the application, Applicants submit the current proposed amendments, which should serve to obviate the Examiner's concerns.

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The Examiner states that "the recitation "emb5" in claims 1 and 17 render the claims indefinite". Applicants presume that the Examiner is referring to claims 1 and 14 and rejects these claims for alleged indefiniteness. Applicants respectfully maintain that it is routine in the art to search for sequences that are homologous to a given gene (for example, to search for rice or wheat homologues of the maize *emb5* sequence identified in the specification by the public accession number M90554), and that one of ordinary skill in the art would be fully capable of cloning the promoters of such *emb5* homologues. To expedite allowance of the application, however, Applicants propose amendment of claims 1 and 14 to recite "the maize *emb5* gene". Support for the proposed amendment is found, for example, on page 24, lines 17 - 27:

The 5' regulatory region of a maize embryo-specific *emb5* gene was isolated from genomic DNA of a public maize line Missouri 17 (MO17). Oligonucleotide primers of SEQ ID NO:2 and SEQ ID NO:3 for the PCR reaction were designed based upon a public protein sequence for maize *emb5* (Williams and Tsang, *Plant Physiol.*, 100:1067-1068, 1992; MZEEMBIV; accession number M90554) and were used to PCR amplify the a portion of the *emb5* promoter from MO17 genomic DNA. The cloned fragment was used as a probe against maize MO17 genomic DNA lambda FIX II from which a genomic clone containing additional *emb5* promoter sequence was isolated. Addition PCR using PCR primers EMPRO-433 (SEQ ID NO:4) and EMPRO-1 (SEQ ID NO:5) and standard cloning procedures were used to clone the *emb5* promoter having the sequence of SEQ ID NO:1 contained in a vector designated pEMpro.

The Examiner has rejected claim 5 for alleged indefiniteness of the phrase "general production or protection of next generation tissues". Claim 5 has been amended for clarity to delete this language.

In view of the proposed amendments submitted herein for clarity, Applicants believe that the Examiner's rejections under 35 USC §112, second paragraph, are made moot, and respectfully request that the rejections be withdrawn. The Examiner has withdrawn all other rejections under 35 USC §112, second paragraph, for which Applicants thank the Examiner.

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**CLAIMS COMPLY WITH THE WRITTEN DESCRIPTION REQUIREMENT UNDER 35 USC §112,  
FIRST PARAGRAPH**

The Examiner has rejected claims 1, 3 – 14, and 16 – 18, under 35 USC §112, first paragraph, as failing to comply with the written description requirement. Applicants respectfully maintain that claims 1, 3 – 14, and 16 – 18 as originally filed, and as previously amended, comply with the written description requirement of 35 USC §112, first paragraph. Nonetheless, in the interest of advancing examination, claims 1, 3, 5, 14, 16, and 18 have been amended to more clearly define the invention. More particularly, Applicants propose amendment for clarity of claims 1 and 14 to recite a promoter derived from the 5' regulatory region of "the maize *emb5* gene", for which abundant support is provided in the specification.

The Examiner alleges that the specification does not sufficiently describe a promoter including about 100 to about 1650 contiguous nucleotides of DNA having from 85% to 100% sequence identity to at least one segment of SEQ ID NO:1. The Examiner further states that the specification "has identified a maize gene and named it "emb5" based only on its expression pattern". The Examiner goes on, "The specification does not describe other information about this gene, necessary to identify emb5 homologs, and therefore their promoters."

Applicants respectfully disagree, and point out the references summarized and cited in the specification (Williams and Tsang (1994) *Dev. Genetics*, 15:415-424; and Williams and Tsang (1992) *Plant Physiol.*, 100:1067-1068) which are in the prior art and contain descriptions of the maize *emb5* sequence and expression pattern. The specification further provides a working example of isolating a promoter of the invention based on the maize *emb5* sequence referenced by its GenBank accession number. Thus, Applicants respectfully traverse the rejection on the same grounds previously presented, but propose amendment of claims 3, 16, and 18 in order to advance prosecution. The amendment as proposed should resolve the Examiner's concerns.

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**CLAIMS COMPLY WITH THE ENABLEMENT REQUIREMENT UNDER 35 USC §112, FIRST PARAGRAPH**

Under the action's heading "Enablement", the Examiner has rejected claims 1, 3 – 14, and 16 – 18, under 35 USC §112, first paragraph, as failing to comply with the "written description requirement". Applicants presume that the Examiner has rejected the listed claims for failing to comply with the enablement requirement. Applicants respectfully maintain that claims 1, 3 – 14, and 16 – 18, as originally filed and as previously amended, comply with the enablement requirement of 35 USC §112, first paragraph.

The Examiner states that one "cannot confirm that a promoter belongs to a homolog of the maize *emb5* gene, without knowledge of its function", and continues, "the specification does not provide any guidance in what nucleotides of SEQ ID No. 1 may be changed, and how to change them, without abolishing promoter function." Applicants respectfully disagree. Applicants maintain that the specification clearly provides an identified sequence for a maize *emb5* gene, which one skilled in the art would know to use as the basis for a routine homology search in non-maize sequences (such as of wheat or of rice, which are explicitly listed in the specification) and to clone the promoters of such identified *emb5* homologues (using procedures similar to those described in Example 1). Furthermore, the specification fully enables methods for detecting promoter activity in plant embryos, including transgenic plant embryos. Applicants reiterate that Examples 2, 3, 4, and 5 describe further examples of actual reduction to practice in support of the claims, including details of experimental procedures for detecting promoter activity, and especially embryo-specific promoter activity, by operably linking a given nucleotide sequence (for example, derivatives or fragments of SEQ ID NO:1) to a reporter gene such as *uidA* or GUS. Applicants maintain that one skilled in the art would recognize these as ordinary and routine experiments. Applicants do not contest that "even minor changes to a promoter can alter or eliminate its activity", but maintain that the necessary experimentation to test a given sequence for promoter activity is neither undue nor non-routine, and therefore respectfully maintain their traversal. Nonetheless, in order to progress toward allowance, Applicants submit the proposed amendments to more clearly define the invention.

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Claims 1, 14, and 18 now recite a promoter derived from the 5' regulatory region of a maize *emb5* gene. Claims 3, 16, and 18 now recite about 100 to about 1650 contiguous nucleotides of SEQ ID NO:1. The claims are fully supported by the specification as originally filed.

Applicants thank the Examiner for consideration of the proposed amendments and respectfully request entry of the amendments. Applicants believe that entry of the amendments proposed herein for clarity, would meet the Examiner's concerns, and respectfully request that the rejections be withdrawn. Applicants respectfully submit that the claims are ready for examination and in condition for allowance.

If the Examiner has any questions regarding this application, the Examiner is encouraged to contact Applicants' undersigned agent at (860) 572-5217 (telephone) or (860) 572-5280 (fax).

Respectfully submitted,



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